



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,607	01/30/2001	Ib Jonassen	4409-214-US	2082

23650 7590 03/29/2005

NOVO NORDISK, INC.  
PATENT DEPARTMENT  
100 COLLEGE ROAD WEST  
PRINCETON, NJ 08540

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/772,607

Applicant(s)

JONASSEN ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 48-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-55 and 57-59 is/are rejected.
- 7) ☒ Claim(s) 56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/15/04.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 20050204.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1653

### **DETAILED ACTION**

1. The finality of the previous Office Action dated March 18, 2004 is withdrawn due to a new ground rejection.

#### ***Status of the Claims***

2. Claims 48-59 are pending.

Applicants' amendment filed December 15, 2004 is acknowledged. Applicants' response has been fully considered. Claims 48-59 are examined.

#### ***Information Disclosure Statement (IDS)***

3. The IDS filed December 15, 2004, which are the same as those filed January 2, 2004 and January 30, 2001, have been initialed and attached.

#### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

4. The previous rejection of claims 48-55 and 34-46 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicants' response at pages 4-7 in the amendment filed December 15, 2004.

#### ***Claim Rejections-Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

5. Claims 48-55 and 57-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 14 and 15 of co-pending application 09/757,788 (US 2001/0012829). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 48-55 and 57-59 in the instant application disclose a derivative of GLP-1 or an analog thereof having a lipophilic substituent which contains 8 to 40 carbon atoms, optionally has an amino group, and is attached to the C-terminal amino acid of GLP-1 or analog thereof optionally via a spacer, wherein the spacer is Lys, Glu, Asp, Glu-Lys or Asp-Lys; and the specification of the instant application discloses a pharmaceutical composition comprising the derivative of GLP-1 or an analog thereof and a carrier (pages 7). This is obvious in view of claims 1-3, 5-7, 14 and 15 of the co-pending application which disclose a formulation suitable for pulmonary administration to a subject, said formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 4-40 carbon atoms via spacer. Since both sets of claims are directed to a derivative of GLP-1 or an analog thereof having a lipophilic substituent, or a formulation containing the GLP-1 derivative. Therefore, claims 48-55 and 57-59 in instant application and claims 1-3, 5-7, 14 and 15 of the co-pending application are obvious variations of a derivative of GLP-1 or an analog thereof having a lipophilic substituent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 48-55 and 57-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending application 10/285,079 (US 2003/0199672). Although the conflicting claims are not identical, they are not

Art Unit: 1653

patentably distinct from each other because claims 48-55 and 57-59 in the instant application disclose a derivative of GLP-1 or an analog thereof having a lipophilic substituent which contains 8 to 40 carbon atoms, optionally has an amino group, and is attached to the C-terminal amino acid of GLP-1 or analog thereof optionally via a spacer, wherein the spacer is Lys, Glu, Asp, Glu-Lys or Asp-Lys; and the specification of the instant application discloses a pharmaceutical composition comprising the derivative of GLP-1 or an analog thereof and a carrier (pages 7). This is obvious in view of claim 1 of the co-pending application which disclose a pharmaceutical composition comprising a GLP-1 derivative of formula I; a C-1-6 ester thereof; an amide, C-1-6 -alkyl amide, or C-1-6-dialkylamide thereof; or a pharmaceutically acceptable salt; wherein amino acids at position 37-43 or 44 can be deleted, the derivative of GLP-1 contains only one or two Lys, the  $\epsilon$ -amino group of Lys substituted with a lipophilic substituent optionally via a spacer, and the total number of different amino acids of the GLP-1 derivative does not exceed six as compared to the native form of GLP-1. Since both sets of claims are directed to a derivative of GLP-1 or an analog thereof having a lipophilic substituent, or a pharmaceutical composition containing the GLP-1 derivative. Therefore, claims 48-55 and 57-59 in instant application and claim 1 of the co-pending application are obvious variations of a derivative of GLP-1 or an analog thereof having a lipophilic substituent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1653

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 48 and 49 are rejected under 35 U.S.C. 102(b) as anticipated by Habener (U.S. Patent 5,118,666, publication date: June 2, 1992).

Habener teaches a GLP-1 derivative having a formula  $H_2N-X-CO-R^1$ , where X is the peptide comprising the sequence His-Ala-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys-Arg;  $R^1$  is OH, OM or  $-NR^2R^3$ ; and M is a pharmaceutically acceptable cation or a lower branched or unbranched alkyl group;  $R^2$  and  $R^3$  are hydrogen or a lower branched or unbranched alkyl group (column 3, lines 6-46). Since the art recognizes the lower alkyl group can be  $C_{1-8}$  or  $C_{1-12}$  (see the reference in the Art of Record), and the lower alkyl group is attached to the C-terminus amino acid without a spacer, thus the GLP-1 derivative taught by Habener *et al.* meets the criteria of claims 48 and 49.

#### ***Claim Objection***

8. Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1653

***Conclusions***

9. Claims 48-55 and 57-59 are rejected, and claim 56 is objected to.

***Art of Record***

Martin et al. (U.S. Patent 5,466,458) teach in compounds of lower alkyl esters, lower ketones, lower alkanols, and lower alkanes, the term "lower" meaning C1-12, preferably C1-10 and more preferably C1-8 (column 8, lines 22-25).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

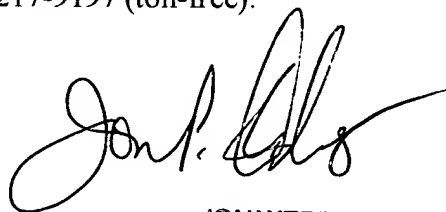
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner

CMK

CMK  
March 16, 2005



**JON WEBER  
SUPERVISORY PATENT EXAMINER**